

Product Proposal

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Owner: Head of R&D

Template Version: 2

1. Summary

1.1. Product id

ARC

1.2. Product description

ARC is used to detect atrial fibrillation (AF) as a risk factor for stroke as reliably as possible. The core of ARC is the analysis algorithm based on AI (artificial Intelligence). It evaluates long-term ECG data and identifies patients with acute AF or an increased probability of paroxysmal AF. The user receives an analysis report including a 5-minute ECG section with the result, which can optionally be automatically transferred to an HIS. The results of the analysis serve as a decision support for the diagnosis by a physician. ARC cannot replace a medical diagnosis. Therefore, never use ARC as the sole basis for your diagnosis and treatment decision.

1.3. Product Owner

Oliver Berger

2. Product plan

2.1. Market analysis

2.1.1. Target market

- The system is primarily intended to replace the existing SRA and SRA+ analysis.
- The system is to be used in clinical and outpatient settings.
- The approval is initially planned for the scope of the MDR. In perspective, possibly also the US market.

2.1.2. Target group

- Clinics or physicians in private practice who examine patients for cardiological disease patterns.

2.1.3. Similar products

There are no really comparable products that can use different holter and monitoring systems for analysis and findings support and can perform a full ECG evaluation. The products each cover only one aspect of the ARC product. The following classification or categorization (without claim to completeness of the products and manufacturers mentioned)

1. products that evaluate ECG analyses on the basis of an AI algorithm (only for own Holter)
 - Cardiologs
 - Cardiometric
 - Preventice Solutions
2. products that do analysis based on wearables and smart phones (single-lead ECGs with no potential for full ECG analysis).
 - CardioCoach
 - Preventicus
 - Rithmi
 - Fibrichck
3. services that combine specific Holter and analysis and offer them to office-based physicians
 - MySmartHeart
4. holter manufacturers with combined ECG analysis
 - Philips ePatch
 - Zio-iRhythm
 - Zenicor
5. implantable loop recorders
 - Medtronic

2.2. Staff

- RA
- PO
- R&D

2.3. Hardware and Software

- Cloud provider

3. Approval

Approver	Date	Sign
CEO		
QMB		
Product owner		